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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
09/716,960	11/21/2000	Michael Brines	10165-009-999	6595				
20583 JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017	7590 10/16/2007		<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">DEBERRY, REGINA M</td></tr></table>		EXAMINER		DEBERRY, REGINA M	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/716,960		BRINES ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Regina M. DeBerry		1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,9,11-15,17-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6,9,15,17-20 and 22 is/are allowed.
- 6) ☒ Claim(s) 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/01</u> .  | 6) <input type="checkbox"/> Other: _____                          |

***Status of Application, Amendments and/or Claims***

The amendment filed 01 August 2007 has been entered in full. Claims 7, 8, 10, 16, 21 and 23-27 are canceled. Claims 1-6, 9, 11-15, 17-20 and 22 are pending and under examination.

***Withdrawn Objections And/Or Rejections***

Claims 1-6, 9, 11-15, 17-20, 22-26 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, as set forth at pages 2-6 of the previous Office Action (01 February 2007), is *withdrawn* in view of the amendment (01 August 2007).

The rejection to claims 1, 12, 15 and 24 under 35 U.S.C. 112, second paragraph, as set forth at page 10 of the previous Office Action (01 February 2007), is *withdrawn* in view of the amendment (01 August 2007).

***Information Disclosure Statement***

The information disclosure statement(s)(IDS) filed 01 August 2007 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

**NEW CLAIM REJECTIONS/OBJECTIONS**

**Claim Rejections-35 USC § 112, First Paragraph, Written Description (New Matter)**

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed:

“A method for protection of neuronal tissue from injury or tissue damage, comprising administering peripherally to said mammal an amount of EPO effective for the protection of the neuronal tissue, wherein the EPO is administered prior to a medical or surgical procedure, wherein said administering does not result in a toxic increase in hemoglobin concentration or hematocrit in said mammal” (claim 11)

“wherein the EPO is administered at least one time 4 hours to 24 hours prior to the medical or surgical procedure” (claim 12)

“wherein the medical procedure is labor or childbirth (claim 13) or

“wherein the surgical procedure is tumor resection, aneurysm repair or a coronary artery bypass procedure” (claim 14).

Applicant's amendment, filed 01 August 2007, asserts that no new matter has been added. Applicant directs support for claim 11 to pages at page 18, line 33 to page

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19, line 18, especially page 19, lines 16-18; support for claim 12 at Section 8 (Example 30), especially page 32, lines 9-13; and Section 13 (Example 8), especially page 35, lines 16-20 and Figure 8B, support for claim 13 at Section 5.2.2, especially page 14, lines 10-14 and lines 24-26 and support for claim 14 at page 18, line 33 to page 19, line 18, especially page 19, lines 16-18 for the written description for the above-mentioned "limitations". The wording or connotation of the instant claim(s) is not readily apparent from said sections.

The Examiner has found the following limitations, "risk of neurological damage induced by labor may be reduced by prophylactically treatment of the fetus before or during labor" (page 14, lines 24-26) and "EPO may be administered to prevent injury or tissue damage resulting from risk of injury or tissue damage during surgical procedures such as for example tumor resection or aneurysm repair"(page 5, line 35-page 6, line 2 and page 19, lines 16-18) . The Examiner has NOT found the following limitations:

"wherein the EPO is administered prior to a medical or surgical procedure"

"wherein the EPO is administered at least one time 4 hours to 24 hours prior to a medical procedure or labor or childbirth"

"wherein the EPO is administered at least one time 4 hours to 24 hours prior to a surgical procedure or tumor resection or aneurysm repair or a coronary artery bypass procedure"

"wherein the surgical procedure is coronary artery bypass procedure".

The specification as filed does not provide a written description or set forth the metes and bounds of this "limitations". The instant claims now recite limitations, which

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were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

### **Conclusion**

Claims 11-14 are rejected

Claims 1-6, 9, 15, 17-20 and 22 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



RMD  
10/11/07



MARIANNE P. ALLEN  
PRIMARY EXAMINER

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10/12/07